K131038

MAY 9 2013

26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

www.navilystmedical.com

510(k) Summary for the PICC Maximal Barrier Nursing Kit

Date prepared: 11 April 2013

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Marion W. Gordon Sr. Project Manager Global Regulatory Affairs Phone: 508-658-7942	or	Lorraine M. Hanley Vice President Global Regulatory Affairs Phone: 508-494-1129

C. Device Name

Trade Name:	PICC Maximal Barrier Nursing Kits
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Catheter, Intravascular Therapeutic, short and long-term greater than 30 days 21 CFR §880.5970, Class II
Classification Panel:	General Hospital Device Panel

D. Predicate Device

Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Catheter, Intravascular Therapeutic, short and long-term greater than 30 days 21 CFR §880.5970, Class II
Premarket Notification	K122882, K121089, K111906, K093366, K091261, K070002

E. Device Description

The PICC Maximal Barrier Nursing Kit is a packaging configuration containing a specified NMI PICC, along with (1) procedural aides typically used for PICC placement and (2) *maximal barrier precaution* devices based upon recommendations of Center of Disease Control and Prevention (CDC).

F. Intended Uses

- PICC Maximal Sterile Barrier Kit with NMI HPICC III

NON-VALVED VERSION

The NMI HPICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for central venous pressure monitoring and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

- PICC Maximal Sterile Barrier Kit with NMI PICC III

NON-VALVED VERSION

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec

VALVED VERSION

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

- PICC Maximal Sterile Barrier Kit with Xcela® Hybrid with PASV® Valve Technology:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

- PICC Maximal Sterile Barrier Kit with NMI PICC II; or with NMI PICC; or with BSC PICC:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

Similarities

The proposed PICC Maximal Barrier Nursing Kit contains one of the identified predicate PICCs packaged with a variety of procedural aide componentry typically used during PICC placement. The proposed PICC indications for use, technological characteristics, materials and operating principles are identical.

Differences

The proposed packaging configuration differs from the predicate PICC kit packaging in order to contain a selection of procedural aides used in PICC placement including those identified as maximal barrier precaution devices. All packaging is manufactured from packaging materials that are well characterized and commonly used in the medical industry.

H. Performance

- No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. The performance evaluation of the PICC Maximal Barrier Nursing Kit was conducted based upon a risk analysis and included testing conducted in accordance with the following national/international standards and FDA guidance documents:
- AAMI/ANSI/ISO 10993-7 *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals* (2008)
- AAMI/ANSI/ISO 11607-1 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* (2006)
- AAMI/ANSI/ISO 11607-2 *Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes* (2006)
- *Deciding When to Submit a 510(k) for a Change to an Existing Device,* 10 January 1997
- *Convenience Kits, Interim Regulatory Guidance: 20 May 1997*
- *Sterilized Convenience Kits for Clinical and Surgical Use: 7 January 2002*
- *Bundling Multiple Devices or Multiple Indications in a Single Submission: 22 June 2007*

I. Safety and Performance Testing

The successful results of the following key tests demonstrate that the proposed PICC Maximal Barrier Nursing Kit has met the pre-determined acceptance criteria applicable to the safe use of the devices.

Tests:
1. Packaging Standards Testing
2. EO Sterilization Testing

J. Conclusion

Results of testing according to recognized standards and in consideration to the responses posed in FDA's *Guidance on the CDRH Premarket Notification Review Program, 510(k) Decision Making Tree,* the proposed PICC Maximal Barrier Nursing Kit is determined to be substantially equivalent to the predicate NMI PICCs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 9, 2013

Ms. Marion W. Gordon
Senior Project Manager
Navilyst Medical, Incorporated
26 Forest Street
MARLBOROUGH, MA 01752

Re: K131038
Trade/Device Name: PICC Maximal Barrier Nursing Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 11, 2013
Received: April 17, 2013

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

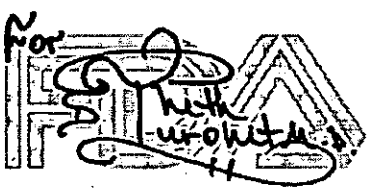
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): _____

Device Name: PICC Maximal Barrier Nursing Kit

with NMI PICC III

Indications for Use:

NON-VALVED VERSION

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec

VALVED VERSION

The NMI PICC III with PASV Vale Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Kathleen E. Fitzgerald

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131038

Indications for Use

510(k) Number (if Known): _____

Device Name: PICC Maximal Barrier Nursing Kit

with NMI HPICC III

Indications for Use:

NON-VALVED VERSION

The NMI HPICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for central venous pressure monitoring and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kathleen E. Fitzgerald

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Date: 2013.05.09 15:27:55 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131038

Indications for Use

510(k) Number (if Known): K131038

Device Name: PICC Maximal Barrier Nursing Kit

with Xcela® Hybrid PICC with PASV® Valve Technology

Indications for Use:

for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
2013.05.07 12:39:02
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131038

Indications for Use

510(k) Number (if Known): _____

Device Name:

PICC Maximal Barrier Nursing Kit
with NMI PICC II
Or

PICC Maximal Barrier Nursing Kit
with NMI PICC
Or

PICC Maximal Barrier Nursing Kit
with BSC PICC

Indications for Use:

for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kathleen E. Fitzgerald

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Date: 2013.05.09 15:27:31 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131038